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(54) Device and method for anastomosis of blood vessels

(57) An anastomosis member has a generally cylindrical body comprising a plate member to be brought into contact with first and second blood vessels. The plate member is arranged in contact with the first and the second blood vessels at an anastomosed site where the first and the second blood vessels are anastomosed to each other. The plate member is provided with a plurality of protrusions formed on at least one of opposite surfaces thereof. The protrusions are engaged with at least one of the first and the second blood vessels to avoid the dislocation of the first and the second blood vessels at the anastomosed site.

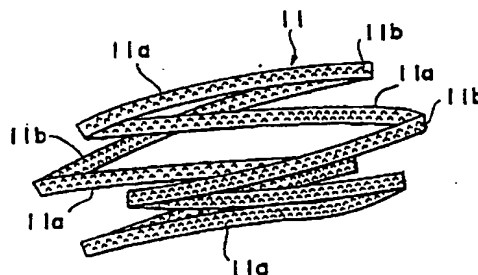


FIG. 1

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Description

Background of the invention:

[0001] This invention relates to an anastomosis member for anastomosing blood vessels and an anastomosis method using the anastomosis member.

[0002] An anastomosis member serves to perform the anastomosis of two normally distinct hollow organs, such as blood vessels, to form a passage therethrough.

[0003] In a conventional surgical operation, the anastomosis of the blood vessels is generally carried out by suturing with a needle and a suture filament. When the blood vessels are anastomosed or joined to each other, a blood flow must temporarily be interrupted. If an increased number of sites are required to be anastomosed, the time of interrupting the blood flow is unfavorably extended.

[0004] In the surgical operation of a living body, it is required to use auxiliary means such as extracorporeal circulation or controlled hypothermia if it is presumed that the time of interrupting the blood flow exceeds an allowable time for the living body. It is difficult to suture the blood vessels under arteriosclerosis with the needle and the suture filament if those vessels have calcification. In case where the blood vessels are fragile, they must be reinforced to avoid the risk.

[0005] The technique of using a stent in the anastomosis of the blood vessels with heavy calcification is reported. In this technique, an artificial blood vessel is inserted into a host blood vessel to partially overlap each other. The stent is retained in the blood vessels at the overlapping portion to press-fit the blood vessels to each other. Thus, the anastomosis is carried out. For example, a type of the stent is disclosed in U.S. Patent No. 6,017,362.

[0006] In the technique of anastomosing the blood vessels by the use of the stent, the blood vessels are simply press-fitted by the elasticity of the stent and may be undesirably released from each other by, for example, the beat of the artery. Thus, the anastomosis by the use of the existing stent is insufficient in fixing or engaging force and in reliability.

Summary of the invention:

[0007] It is therefore a technical object of this invention to provide an anastomosis member capable of safely and quickly carrying out the anastomosis of blood vessels and to provide an anastomosis method using the anastomosis member.

[0008] It is another object of this invention to provide an anastomosis member improved in reliability by the use of a technique of applying an engaging force only to an adventitia of a blood vessel which is stronger than an intima of the blood vessel and to provide an anastomosis method using the anastomosis member.

[0009] It is still another object of this invention to

provide an anastomosis member capable of carrying out the anastomosis of blood vessels substantially equal in outer diameter and in inner diameter and to provide an anastomosis method using the anastomosis member.

[0010] According to this invention, there is provided an anastomosis member to be arranged at an anastomosed site of first and second blood vessels to carry out the anastomosis of the first and the second blood vessels, the anastomosis member having a generally cylindrical body comprising at least one plate member to be brought into contact with both of the first and the second blood vessels, the plate member having a plurality of protrusions formed on at least one of opposite surfaces thereof to be engaged with at least one of the first and the second blood vessels so as to prevent the dislocation of the first and the second blood vessels at the anastomosed site.

[0011] Preferably, the anastomosis member has a plurality of the generally cylindrical bodies and at least one connecting member connecting the generally cylindrical bodies to one another.

[0012] Preferably, the anastomosis member has an elasticity so as to be compressed and expanded in diameter.

[0013] Preferably, the anastomosis member has a stress-strain characteristic including a plurality of different kinds of regions at least corresponding to a low-rigidity part deformable along the curvatures of the first and the second blood vessels to be tightly fitted thereto, and a spring region which is compressible and self-expandable in diameter.

[0014] Preferably, the generally cylindrical body comprises a plurality of the plate members connected to one another in a zigzag pattern.

[0015] Preferably, the generally cylindrical body comprises at least one plate member wound into a helical shape.

[0016] Preferably, the generally cylindrical body comprises a plurality of the plate members connected to one another in a lattice pattern.

[0017] Preferably, the generally cylindrical body comprises a plurality of the plate members connected to one another in a rhombic pattern.

[0018] Preferably, the generally cylindrical body comprises a plurality of the plate members arranged in parallel to one another and a plurality of connecting members connecting the plate members to one another.

[0019] Preferably, each of the connecting members is an elastic wire member.

[0020] Preferably, the plate member is made of a stainless steel plate or a shape memory alloy selected from a TiNi alloy and a beta Ti alloy.

[0021] According to this invention, there is also provided an anastomosis device for use in the anastomosis of first and second blood vessels, the anastomosis device comprising a combination of an anastomosis member arranged on an outer surface of at least one of

the first and the second blood vessels and a stent to be arranged in a lumen of the at least one of the first and the second blood vessels, the anastomosis member having a generally cylindrical body comprising at least one plate member to be brought into contact with both of the first and the second blood vessels, the plate member having a plurality of protrusions formed on at least one of opposite surfaces thereof to be engaged with at least one of the first and the second blood vessels.

[0022] Preferably, the stent is made of a stainless steel plate or a shape memory alloy selected from a TiNi alloy and a beta Ti alloy.

[0023] Preferably, the anastomosis device further comprises an additional blood vessel.

[0024] According to this invention, there is also provided an anastomosis method for the anastomosis of first and second blood vessels by the use of an anastomosis member to be arranged at an anastomosed site of the first and the second blood vessels, the anastomosis member having a generally cylindrical body comprising a plate member with a plurality of protrusions formed on at least one of opposite surfaces thereof, the method comprising the steps of inserting the anastomosis member into lumens of the first and the second blood vessels; bringing the plate member into contact with at least one of the first and the second blood vessels; and engaging the first and the second blood vessels with the protrusions so as to prevent the dislocation of the first and the second blood vessels at the anastomosed site.

[0025] Preferably, the anastomosis method further comprises the steps of inserting an end portion of one of the first and the second blood vessels into the lumen of the other blood vessel so that the end portions of the first and the second blood vessels overlap each other with the protrusions engaged with at least one of the first and the second blood vessels.

[0026] According to this invention, there is provided an anastomosis method for the anastomosis of first and second blood vessels by the use of an anastomosis device to be arranged at an anastomosed site of the first and the second blood vessels, the anastomosis device comprising a combination of an anastomosis member and a stent, the anastomosis member comprising a plate member with a plurality of protrusions formed on at least one of opposite surfaces thereof, the method comprising the steps of inserting the stent into an end portion of a lumen of one of the first and the second blood vessels; inserting the end portion of the one of the first and the second blood vessels into an end portion of a lumen of the other of the first and the second blood vessels; inserting the anastomosis member so that the anastomosis member is interposed between the first and the second blood vessels at an anastomosed site where the first and the second blood vessels overlap each other; bringing the protrusions into contact with the first and the second blood vessels; press-fitting by the stent the first and the second blood vessels at the

anastomosed site; engaging the first and the second blood vessels with the protrusions so as to prevent the dislocation of the first and the second blood vessels at the anastomosed site.

[0027] Preferably, each of the plate members is sutured by a fastening member to one of the first and the second blood vessels in at least one position in the anastomosed site, the protrusions being formed only on one surface of the plate member which faces the other of the first and the second blood vessels at the anastomosed site.

[0028] According to this invention, there is also provided an anastomosis method for the anastomosis of first and second blood vessels by the use of an anastomosis device to be arranged at an anastomosed site of the first and the second blood vessels, the anastomosis device comprising a combination of an anastomosis member and a stent, the anastomosis member comprising a plate member with a plurality of protrusions formed on at least one of opposite surfaces thereof, the method comprising the steps of inserting the stent to extend over lumens of the first and the second blood vessels; abutting the first and the second blood vessels to each other; arranging the anastomosis member around outer surfaces of the first and the second blood vessels; bringing the protrusions into contact with an adventitia of each of the first and the second blood vessels; and engaging the first and the second blood vessels with the protrusions so as to prevent the dislocation of the first and the second blood vessels at the anastomosed site.

[0029] Preferably, the anastomosis method further comprises the steps of placing an additional blood vessel on the outside of the anastomosis member arranged around the outer surfaces of the first and the second blood vessels; and engaging the anastomosis member and the additional blood vessel with the protrusions.

[0030] Preferably, the additional blood vessel is fastened by a fastening member in at least one position.

[0031] Preferably, the fastening member is a filament or a strap.

Brief Description of the Drawing:

[0032]

Fig. 1 is a perspective view of an anastomosis member according to a first embodiment of this invention;

Fig. 2 is a perspective view of an anastomosis member according to a second embodiment of this invention;

Fig. 3 is a perspective view of an anastomosis member according to a third embodiment of this invention;

Fig. 4 is a perspective view of an anastomosis member according to a fourth embodiment of this invention;

ments, the plate member 14a is provided with a plurality of protrusions 14b formed on its opposite surfaces.

[0044] For example, each of the plate members 14a comprises a stainless steel plate subjected to annealing and having a low rigidity. For example, each of the plate members 14a has an axial length of 10mm, a thickness of 0.2mm, and a width of 1.2mm. The anastomosis member 14 has a diameter of 8mm. Each of the connecting members 14c comprises a stainless steel wire (SUS304WP) having a length of 2mm and a diameter of 0.2mm. In this embodiment, the connecting members 14c comprise spring wires which are equal in length to each other and each of which is bent to form an angled portion having an acute angle.

[0045] Specifically, the anastomosis member 14 has a low-rigidity part (plate members 14a) deformable along the curvatures of first and second blood vessels (Fig. 10, 33 and 34) to be tightly fitted thereto, and a self-expandable spring part (connecting members 14c). Thus, the anastomosis member 14 has a stress-strain characteristic including at least two different kinds of regions.

[0046] The protrusions 14b are formed on the opposite surfaces of each plate member 14a. The plate members 14a and the connecting members 14c are welded to each other to form the generally cylindrical body as the anastomosis member 14. The anastomosis member 14 can be expanded and compressed by changing the angles of the angled portions of the connecting members 14c.

[0047] As described above, the plate members 14a and the connecting members 14c are different from each other in stress-strain characteristic. The plate members 14a are soft and low in rigidity. Therefore, the anastomosis member 14 is readily deformable in conformity with the curvatures of the first and the second blood vessels without local pressure concentration in the first and the second blood vessels. Thus, the anastomosis member 14 can uniformly apply the pressure upon the first and the second blood vessels. Because of presence of the protrusions 14b, the anastomosis member 14 can be engaged with the first and the second blood vessels with a large frictional force.

[0048] It is noted here that the shape of the anastomosis member 14 is not restricted to that illustrated in Fig. 4. The connecting member 14c can be formed into a rhombic shape or any other appropriate shape as far as the connecting members 14c can hold the plate member 14a and are self-expandable. The plate member 14a is not restricted to the shape described in this embodiment but may have any other appropriate shape matching the configurations of the first and the second blood vessels.

[0049] Referring to Fig. 5, an anastomosis member 15 according to a fifth embodiment of this invention comprises a pair of generally cylindrical bodies connected by a connecting portion 15c. Each of the generally cylindrical bodies is similar in structure to the

generally cylindrical body of the anastomosis member 11 in Fig. 1. The connecting portion 15c is made of a material same as that of plate members 11a.

[0050] Referring to Fig. 6, an anastomosis member 16 according to a sixth embodiment of this invention comprises a pair of generally cylindrical bodies connected by a connecting portion 16c. Each of the generally cylindrical bodies is similar in structure to the generally cylindrical body of the anastomosis member 12 in Fig. 2. The connecting portion 16c is made of a material same as that of plate members 12a.

[0051] Referring to Fig. 7, an anastomosis member 17 according to a seventh embodiment of this invention comprises a pair of generally cylindrical bodies connected by a connecting portion 17c. Each of the generally cylindrical bodies is similar in structure to the generally cylindrical body of the anastomosis member 13 in Fig. 3. The connecting portion 17c is made of a material same as that of plate members 13a.

[0052] Referring to Figs. 8 and 9, an anastomosis member 18 according to an eighth embodiment of this invention comprises a pair of generally cylindrical bodies connected by a connecting portion 18c. Each of the generally cylindrical bodies is similar in structure to the generally cylindrical body of the anastomosis member 14 in Fig. 4. The connecting portion 18c is made of a material same as that of plate members 14a. The connecting portion 18c is smaller in width than each plate member 14a.

[0053] In the foregoing embodiments, the plate members 11a, 12a, 13a, and 14a are provided with the protrusions 11b, 12b, 13b, and 14b formed on both of the opposite surfaces thereof, respectively. Alternatively, the protrusions may be formed on only one of the opposite surfaces thereof. Each of the anastomosis members 11 through 18 is not restricted to the pattern described in each of the foregoing embodiments but may have any appropriate pattern as far as the diameter can flexibly be changed.

[0054] As a material of each of the plate members 11a, 12a, 13a, and 14a in the foregoing embodiments, use may be made of a stainless steel plate, a TiNi alloy and a TiNi-X alloy (X = Cr, V, Cu, Fe, Co, etc) having superelasticity at a living body temperature. Furthermore, use may also be made of a wide variety of shape memory alloys, such as a Cu-based alloy and a Fe-based alloy, as well as a beta Ti alloy. Taking the biocompatibility and the toxicity into consideration, the opposite surfaces of the plate members 11a, 12a, 13a, and 14a may be coated with titanium or the like.

[0055] Now, description will be made of several specific examples of the anastomosis of the first and the second blood vessels.

[0056] Referring to Fig. 10, a first example of the anastomosis will be described. Herein, the anastomosis is carried out by the use of the anastomosis member 11 illustrated in Fig. 1. In the following description, the similar parts are designated by like reference numerals. It

engaged with the intima of the host blood vessel 33 and the adventitia of the artificial blood vessel 34. Thus, the host and the artificial blood vessels 33 and 34 are prevented from being dislocated even under the beat of the artery. Thus, the anastomosis is reliably carried out.

[0070] The stainless steel plate of the anastomosis member 11 is not restricted to SUS316 but may be any other appropriate product having a low rigidity and a flexibility. The material and the shape of the stent 36 are not restricted to those given in this embodiment but may be appropriately selected taking into account the sizes of the host blood vessel 33 and the artificial blood vessel 34 as well as an expanding force of the stent 36.

[0071] Referring to Fig. 13, a fourth example of the anastomosis will be described. Herein, the anastomosis is carried out by the use of a three-piece anastomosis device comprising a combination of the anastomosis member 11 in Fig. 1, a woven tubular stent 46, and an additional blood vessel 55. In this example also, the anastomosis member 11 serves as a securing member for securing the two blood vessels in the anastomosed state. In the following description, similar parts are designated by like reference numerals. It will be noted here that the size of the anastomosis member 11 in this example is slightly different from that mentioned in conjunction with Fig. 1.

[0072] The anastomosis member 11 is attached to the host and the artificial blood vessels 33 and 34. An end face of the artificial blood vessel 34 is abutted to an end face of the host blood vessel 33. The anastomosis member 11 is arranged on outer surfaces of the host and the artificial blood vessels 33 and 34 to extend over both of the host and the artificial blood vessels 33 and 34. The stent 46 is arranged in the lumens of the host and the artificial blood vessels 33 and 34 at an area corresponding to the anastomosis member 11.

[0073] Furthermore, the additional blood vessel 55 is arranged around the host and the artificial blood vessels 33 and 34 to cover the anastomosis member 11. The anastomosis member 11 and the additional blood vessel 55 are engaged with each other by the protrusions 11b. The opposite ends of the additional blood vessel 55 are fastened to the host and the artificial blood vessels 33 and 34 by a filament 57 or a strap as a fastening member. The protrusions 11b may be formed only on one surface of the anastomosis member 11 to be engaged with the host and the artificial blood vessels 33 and 34.

[0074] More specifically, the anastomosis member 11 comprises a strip-like plate member 11a made of a stainless steel plate (SUS316) subjected to annealing and having a low rigidity. The plate member 11a has a thickness of 0.25mm. Each protrusion 11b has a height between 65 and 75 μ m and a diameter of 30 μ m. The protrusions 11b are formed at a pitch of 0.2mm.

[0075] In this example of the anastomosis, the anastomosis member 11 has an inner diameter of 8mm, an axial length of 10mm, and a width of 0.4mm. The

anastomosis member 11 is flexibly variable in shape and in cylindrical diameter.

[0076] The stent 46 is made of a material similar to that of the stent 36 illustrated in Fig. 12 and has a lattice pattern. For example, the stent 46 is designed to have a cylindrical shape with a final expanding diameter of 7mm and an axial length of 20mm.

[0077] In the anastomosis, one axial half of the stent 46 is inserted into the lumen of the artificial blood vessel 34, for example, having an outer diameter of 8mm and an inner diameter of 6mm. Then, the host and the artificial blood vessels 33 and 34 are abutted to each other. Simultaneously, the other axial half of the stent 46 is inserted into the lumen of the host blood vessel 33. The anastomosis member 11 preliminarily ranged on the outside of the artificial blood vessel 34 is positioned to extend over the outer surfaces of both of the host and the artificial blood vessels 33 and 34. Likewise, the additional blood vessel 55 arranged on the outside of the artificial blood vessel 34 is positioned around the anastomosis member 11. The additional blood vessel 55 has an inner diameter of 8.1mm.

[0078] The opposite ends of the additional blood vessel 55 are fastened by the filament 57 as the fastening member to the outer surfaces of the host and the artificial blood vessels 33 and 34. The host and the artificial blood vessels 33 and 34 and the anastomosis member 11 are press-fitted by an internal pressure applied by the stent 46 and an external pressure applied by the additional blood vessel 55 fastened by the filament 57. At this time, the protrusions 11b are engaged with the host and the artificial blood vessels 33 and 34. Thus, the host and the artificial blood vessels 33 and 34 are prevented by the anastomosis member 11 from being dislocated with respect to each other even under the beat of the artery. Therefore, the anastomosis is reliably carried out. Since the additional blood vessel 55 and the filament 57 are fastened to each other, blood leakage from the anastomosed site to the outside is prevented.

[0079] The anastomosis in the above-mentioned example can be manually and quickly carried out by a surgeon so that the time of interrupting the blood flow can be shortened.

[0080] In this example of the anastomosis, the engaging force of the protrusions 11b acts only on the adventitia of each blood vessel which is relatively strong as compared with the intima. Thus, the load upon the host and the artificial blood vessels 33 and 34 is small as compared with the case where the inner surfaces are used in engagement. Furthermore, the host and the artificial blood vessels 33 and 34 need not overlap each other so that the anastomosis is possible even if the host and the artificial blood vessels 33 and 34 are substantially equal in diameter to each other. The anastomosis member 11 can relatively flexibly cope with the difference in size between the host and the artificial blood vessels 33 and 34.

sible to uniformly apply the pressure to the first and the second blood vessels without causing local concentration of the pressure.

Claims

1. An anastomosis member (11 to 18, 111) to be arranged at an anastomosed site of first and second blood vessels (33,34) to carry out the anastomosis of said first and said second blood vessels,

said anastomosis member (11-18, 111) having a generally cylindrical body comprising at least one plate member (11a to 14a) to be brought into contact with both of said first and said second blood vessels,

said plate member having a plurality of protrusions (11b to 14b, 111b) formed on at least one of opposite surfaces thereof to be engaged with at least one of said first and said second blood vessels so as to prevent the dislocation of said first and said second blood vessels at said anastomosed site.

2. An anastomosis member as claimed in claim 1, said anastomosis member (11 to 18) having a plurality of said generally cylindrical bodies and at least one connecting member (14c to 18c) connecting said generally cylindrical bodies to one another.

3. An anastomosis member as claimed in claim 1 or 2, wherein said anastomosis (11 to 18, 111) member has an elasticity so as to be compressed and expanded in diameter and/or a stress-strain characteristic including a plurality of different kinds or regions at least corresponding to low-rigidity part deformable along the curvatures of said first and said second blood vessels (33,34) to be tightly fitted thereto, and a spring region which is compressible and self-expandable in diameter.

4. An anastomosis member as claimed in one of claims 1 to 3, wherein said plate member is made of a stainless steel plate or a shape memory alloy selected from a TiNi alloy and a beta Ti alloy.

5. An anastomosis member as claimed in one of claims 1 to 4, wherein said generally cylindrical body comprises at least one plate member (12a) wound into a helical shape.

6. An anastomosis member as claimed in one of claims 1 to 4, wherein said generally cylindrical body comprises a plurality of said plate members connected to one another in a zigzag pattern (11a) or in a lattice pattern (13a) or in a rhombic pattern (13a) or arranged in parallel to one another and a plurality of connecting members (14c) connecting

said plate members (14a) to one another, said connecting members preferably being an elastic wire member.

7. An anastomosis device for use in the anastomosis of first and second blood vessels (33, 34), said anastomosis device comprising a combination of an anastomosis member (11, 111) arranged on an outer surface of at least one of said first and said second blood vessels and a stent (36, 46, 136) to be arranged in a lumen of said at least one of the first and the second blood vessels, said anastomosis member having a generally cylindrical body comprising at least one plate member (11a, 111a) to be brought into contact with both of said first and said second blood vessels, said plate member having a plurality of protrusions (11b, 111b) formed on at least one of opposite surfaces thereof to be engaged with at least one of said first and said second blood vessels.

8. An anastomosis device as claimed in claim 7, wherein said stent (36, 46, 136) is made of a stainless steel plate or a shape memory alloy selected from a TiNi alloy and a beta Ti alloy.

9. An anastomosis device as claimed in claim 7 or 8, further comprising an additional blood vessel (34, 55).

10. An anastomosis method for the anastomosis of first and second blood vessels (33, 34) by the use of an anastomosis member (11 to 18, 111) to be arranged at an anastomosed site of said first and said second blood vessels, said anastomosis member having a generally cylindrical body comprising a plate member (12a to 14a, 111a) with a plurality of protrusions (11b to 14b, 111b) formed on at least one of opposite surfaces thereof, said method comprising the steps of:

inserting said anastomosis member into lumens of said first and said second blood vessels;

bringing said plate member into contact with at least one of said first and said second blood vessels; and

engaging said first and said second blood vessels with said protrusions so as to prevent the dislocation of said first and said second blood vessels at said anastomosed site.

11. An anastomosis method for the anastomosis of first and second blood vessels (33, 34) by the use of an anastomosis device to be arranged at an anastomosed site of said first and said second blood vessels, said anastomosis device comprising a combination of an anastomosis member (11 to 18,

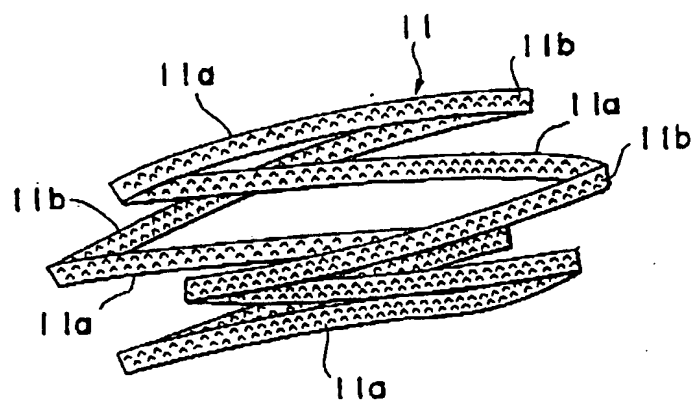


FIG. 1

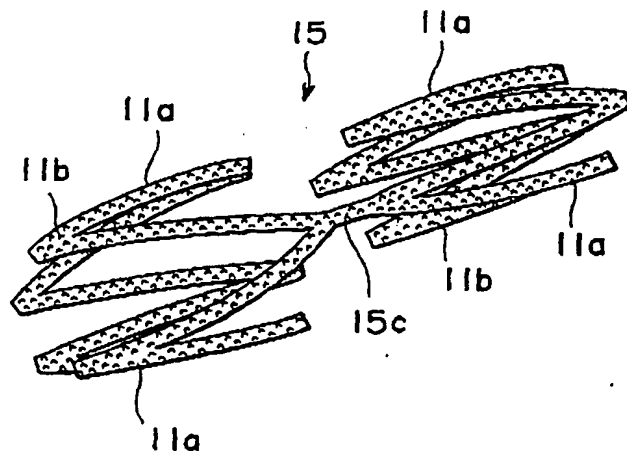


FIG. 5

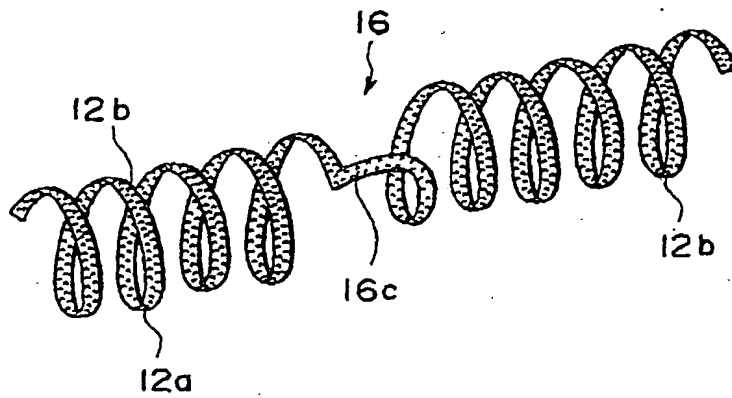


FIG. 6

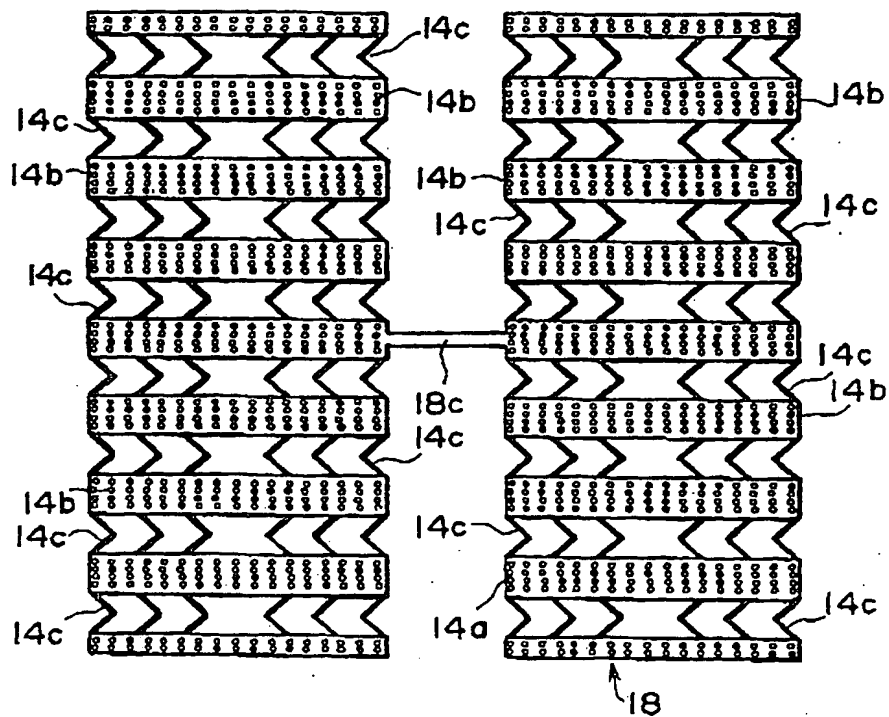


FIG. 9

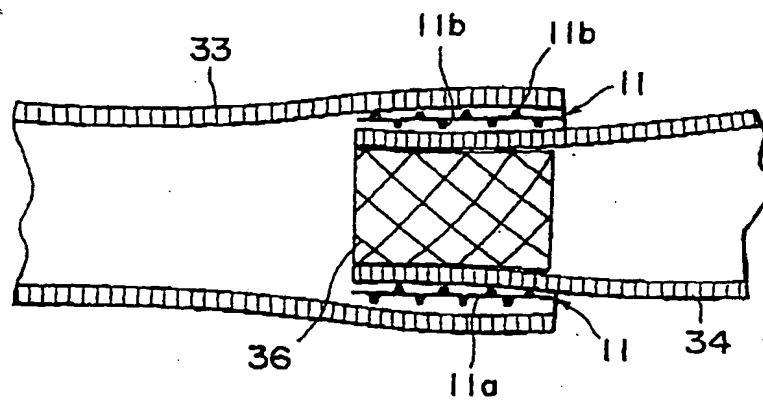


FIG. 12

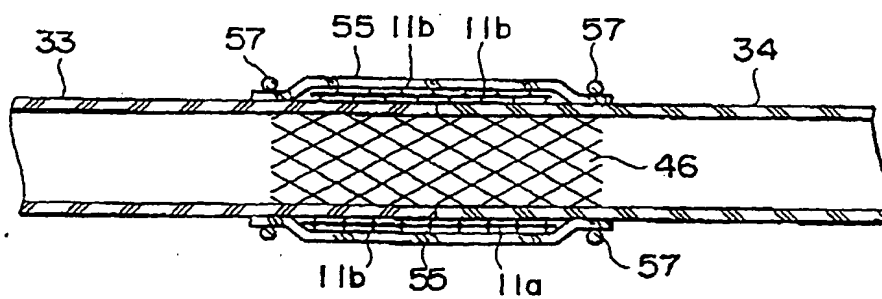


FIG. 13



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Application Number

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

EP 00 11 1401

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			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61F A61B
INCOMPLETE SEARCH <p>The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.</p> <p>Claims searched completely : 1-9</p> <p>Claims searched incompletely : 10-15</p> <p>Reason for the limitation of the search: Article 52 (4) EPC - Method for treatment of the human or animal body by surgery</p>			
Place of search THE HAGUE		Date of completion of the search 31 July 2000	Examiner Mary, C
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**ANNEX TO THE EUROPEAN SEARCH REPORT
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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
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